09 April 2021
EMA/CHMP/188718/2021 Rev.1
Human Medicines Division

Committee for medicinal products for human use (CHMP)

PROM[1] agenda for the meeting on 12 April 2021

Chair: Harald Enzmann – Vice-Chair: Bruno Sepodes

12 April 2021, 09:00–14:30, virtual meeting / room 08-A

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Of note, agendas and minutes are working documents primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

[1] The CHMP PReparatory and Organisational Matters (PROM) is a meeting to discuss CHMP organisational matters and other topics in preparation for the CHMP Plenary meeting. It is a virtual meeting, which usually takes place on Monday before the CHMP Plenary meeting. CHMP members, working party chairs and national experts together with EMA staff are participating in this forum. Depending on the nature of the issue and availability of documents and experts some PROM topics can be discussed at the CHMP Plenary.

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1. Agenda and Minutes

1.1. Welcome and declarations of interest of members, alternates and experts

1.2. Adoption of agenda

CHMP PROM Agenda for 12 April 2021 meeting

1.3. Adoption of the minutes

CHMP PROM Minutes of March 2021 meeting will be adopted at the April 2021 CHMP plenary

2. Non therapeutic-area-specific working parties

2.1. Patients and Consumers Working Party (PCWP) Healthcare Professionals Working Party (HCPWP)

No topics

2.2. Biologics Working Party (BWP)

Chairs: Sol Ruiz/Nanna Aaby Kruse

2.2.1. Agenda and minutes

- Final minutes for BWP meeting held by Adobe Connect on 15-17 February 2021
- Draft agenda for BWP meeting to be held by Adobe Connect on 12-14 April 2021

Action: For information

2.3. Quality Working Party (QWP)

Chairs: Blanka Hirschlerova/Laivi Saaremäel

2.3.1. Minutes

- Final minutes from QWP Core Team meeting held by teleconference on 17 March 2021

Action: For information

2.3.1. CMDh question to QWP on applicability of Q5 to intermediate manufacturers

CMDh question to QWP on possibility to expand the applicability of Q5 of the CMDh Q&A on QP declaration (CMDh/340/2015/Rev.6, July 2020) to also include intermediate manufacturers was adopted on November 2020 ORGAM meeting. The CMDh at its March 2021 plenary meeting agreed to withdraw this question.

Action: For information

2.4. Safety Working Party (SWP)

Chairs: Jan Willem Van der Laan/Susanne Brendler-Schwaab

2.4.1. Minutes

- Final minutes for SWP meeting held by teleconference on 22 February 2021

Action: For information

2.4.2. SWP position on pyrrolizidine alkaloids

SWP position on draft HMPC public statement on herbal medicinal products containing pyrrolizidine alkaloids.

Action: For adoption

2.4.3. Composition of the Nitrosamine expert group

The Nitrosamine expert group is being established to discuss nitrosamine issues with Industry.

Action: For information

2.4.4. EFSA scientific opinion on TiO2

SWP (together with QWP core group) is foreseen review the EFSA opinion on TiO2 and available evidence.

Action: For information

2.5. Biosimilar Medicinal Product Working Party (BMWP)

Chairs: Elena Wolff-Holz/Niklas Ekman

2.5.1. Agenda and minutes

- Agenda of BMWP meeting held virtually on 31 March 2021
- Final minutes for BMWP meetings held by Adobe Connect on 22 October 2020 and 3 February 2021

Action: For information

2.6. Biostatistics Working Party (BSWP)

No topics

2.7. Modelling and Simulation Working Party (MSWP)

Chairs: Kristin Karlsson/Flora Musuamba Tshinanu

2.7.1. Agenda and minutes

- Agenda of MSWP meeting held virtually on 7 April 2021
- Table of Decisions of MSWP meeting held virtually on 3 March 2021

Action: For information

2.7.2. Call for nominations for MSWP chair and MSWP vice-chair

The mandate of MSWP chair Kristin Karlsson and MSWP vice-chair Flora Musuamba Tshinanu will expire on 28 June 2021.

Nominations should be sent to the Agency by **6 May 2021**. Candidates are kindly asked to submit a brief CV in support of their candidature together with a cover letter highlighting their expertise.

Elections will take place at the May CHMP Plenary meeting.

Action: For information

2.8. Pharmacogenomics Working Party (PGWP)

No topics

2.9. Pharmacokinetics Working Party (PKWP)

Chair: Caroline Versantvoort

2.9.1. Product-specific guidelines

Final product-specific guidelines

- Lapatinib product-specific bioequivalence guidance (EMA/CHMP/257298/2018) and Overview of comments (Note: there were two public consultations in the development of this guideline and therefore the overview includes comments from both consultations)
- Acenocoumarol product-specific bioequivalence guidance (EMA/CHMP/512475/2020) (Note: no Overview as no comments received in public consultation)

Action: For adoption

Revision of product-specific guidelines

- Palbociclib product-specific bioequivalence guidance (EMA/CHMP/802679/2018 Rev.1) and Overview of comments

Action: For adoption

2.9.2. PKWP composition

- Iva Klarica Domjanović (HR) to change status from Member to Additional Assessor
- Current Additional Assessor to replace Iva Klarica Domjanović (HR) as Member in line with nomination pending vacancy in April 2019

Action: For endorsement

3. Therapeutic-area-specific working parties and SAGs

3.1. Blood Products Working Party (BPWP)

Chairs: Jacqueline Kerr/Karri Penttilä

3.1.1. Agenda and minutes

- Minutes of the BPWP TC held virtually on 11th March
- Final agenda of the Blood cluster TC held virtually on 19th March
- Draft minutes of the Blood cluster TC held virtually on 19th March

Action: For information

3.1.2. Third party (PPTA and IPFA) request to discuss matters related to plasma for fractionation and plasma-derived medicinal product

Third party (PPTA and IPFA) request for a TC to discuss matters related to plasma for fractionation and plasma-derived medicinal products.

Action: For discussion

3.2. Central Nervous System Working Party (CNSWP)

No topics

3.3. Cardiovascular Working Party (CVSWP)

No topics

3.4. Infectious Diseases Working Party (IDWP)

No topics

3.5. Oncology Working Party (ONCWP)

No topics

3.6. Rheumatology/Immunology Working Party (RIWP)

No topics

3.7. Vaccines Working Party (VWP)

No topics

3.8. Scientific Advisory Groups (SAGs)

No topics

4. Drafting groups

4.1. Excipients Drafting Group

No topics

4.2. Gastroenterology Drafting Group (GDG)

No topics

4.3. Geriatric Expert Group (GEG)

No topics

4.4. Radiopharmaceuticals Drafting Group (RadDG)

No topics

4.5. Respiratory Drafting Group (RDG)

No topics

5. Harmonisation and consistency groups

5.1. International Council on Harmonisation (ICH)

5.1.1. Public consultation for Guideline ICH S1B Step 2b - Testing for Carcinogenicity of Pharmaceuticals - S1B Addendum

Start of 5-month public consultation of the draft Guideline ICH S1B Step 2b - Testing for Carcinogenicity of Pharmaceuticals - S1B Addendum.

Action: For adoption

5.2. Action: For adoption Guideline Consistency Group (GCG)

No topics

5.3. Summary of product characteristics Advisory Group

No topics

6. Joint groups and collaboration with other Scientific committees

6.1. Joint CVMP/CHMP ad-hoc expert group on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of medicinal products (J 3RsWG)

No topics

6.2. Joint CHMP/CVMP/CMDh/CMDv Working Group on Active Substance Master File Procedures (ASMF WG)

No topics

6.3. Collaboration with other Scientific committees

6.3.1. PRAC report to CHMP

Chair: Sabine Straus

Summary of recommendations and advice of PRAC meeting held on 06-09 April 2021.

Action: For information

6.4. Regulatory Issues / new legislation

No topics

6.5. CHMP organisation / templates

6.5.1. CHMP learnings

Collection, discussion and recording of CHMP learnings.

CHMP: Outi Mäki-Ikola

Action: For discussion

6.5.2. Revision of assessment report templates

Revision of the following templates:

- Rapporteurs Assessment report on the claim of new active substance (NAS)
- Full batch of initial marketing authorisation assessment report templates.

Action: For discussion

6.5.3. Management of Written Procedures in emergency situations

Discussion on timelines and logistics for written procedures.

CHMP: Harald Enzmann, Sinan B. Sarac

Action: For discussion

6.5.4. Resourcing of Covid-19 applications: Follow up from February and March CHMP meetings

Update to the CHMP on the progress and next steps on resourcing of Covid-19 applications following discussion at February and March CHMP meetings.

Action: For discussion

6.5.5. Update of Working Parties Review Project

Update on the progress of the Working Party Review Project.

CHMP: Harald Enzmann

Action: For information

7. Product development support

7.1. Scientific Advice Working Party (SAWP)

Chair: Anja Schiel

7.1.1. Appointment of CHMP peer review for SA

Action: For information

7.2. Innovation Task Force

7.2.1. ITF meeting

Meeting date: 21 April 2021

Action: For adoption

7.2.2. ITF meeting

Meeting date: 23 April 2021

Action: For adoption

7.2.3. ITF meeting

Meeting date: 28 April 2021

Action: For adoption

8. Product related topics

8.1.1. Preview CHMP Plenary

CHMP: Harald Enzmann

Action: For information

8.1.2. COVID-19 ongoing and upcoming procedures

List of currently ongoing and upcoming (imminently, i.e. expected within the next 2 months) applications for COVID-19 vaccines and therapeutics.

Action: For information

8.1.3. zanubrutinib - Orphan - EMEA/H/C/004978

BeiGene Ireland Ltd; treatment of Waldenström's macroglobulinaemia (WM)

Scope: Update on the status of this application

Action: For information

8.1.4. evinacumab - EMEA/H/C/005449

treatment of homozygous familial hypercholesterolemia (HoFH)

Scope: Update on the status of this application

Action: For information

9. Any Other Business

9.1.1. Data Standards Strategy survey and workshop

As announced at the EU big data stakeholder virtual forum in December 2020, one of the 10 priority recommendations of the HMA-EMA joint Big Data Task Force (BDTF) is to engage in international initiatives related to data standardisation. This will be critical to realise the full potential of big data to drive regulatory evaluations. With a view to address these BDTF recommendations, the Big Data Steering Group has launched an initiative to develop a **Data Standards Strategy** that will enable the Network to more effectively leverage data to deliver evidence in support of benefit-risk decision-making on the development, authorisation and use of medicines.

Action: For discussion

9.1.2. Results of EMA study on RWE in marketing authorisation applications and extensions of indication

EMA has studied the use of real-world data (RWD) to support centralised MAA and extensions of indication submitted in 2018 and 2019. The primary objective of this study is to characterise RWD/RWE and its contribution to benefit-risk decision-making.

Action: For discussion